

Application # - 10/801,520 Examiner Michele Flood, Art Unit 1655  
Reply to Office Communications dated 2/16/2007

### **Remarks/ Amendments to Comply**

This reply is to a final rejection to place this patent application in condition for allowance. Newly submitted claims 33-63 were subject to review describing a composition, where claims 60-63 were directed to a method with constructive election to original presentation for prosecution on the merits. Claims 60-63 being withdrawn from consideration as to a non-elected invention.

#### **1. Objections: 35 USC 112 (New Matter)**

**Claims rejection for 33-59 are rejected for lack of prior antecedent basis "garlic alone or in combination with propolis" Claim 33 line 5, however the specification as original filed provides for propolis as an optional ingredient as written in [0019] where the use of propolis may replace garlic for individuals who are allergic to garlic. This therefore cludes to new matter.**

**Amendment to overturn rejection:** This was an over-site by improperly written claims in the preceding amendment of which the new matter is now omitted from the claim language and propolis is listed as an optional ingredient in the base claim 33.

#### **2. Objections: 35 USC 112 (Indefinite Claim Language)**

**a. Claims 47, 48 and 59 are rejected under 35 USC 112 2<sup>nd</sup> paragraph for failing to point out and claim the subject matter. Claim 47, line 9 recites the abbreviation for EDTA.**

**Amendment to overturn rejection:** Claim 47 where EDTA has been replaced with the term "ethylenediaminetetraacetic acid" as suggested by examiner.

**b. The metes and bounds of Claim 48 are rendered indefinite because niacin is defined as a constituent selected from the Markush group containing compounds other than niacin.**

**Amendment to overturn rejection.** This has been corrected through amendment to claim 33 and 48. In the original application, Claim 1 established niacin in the base formulation, then also supporting Claim 12 in which niacin was further comprised of one or more selected from the group consisting of "niacinamide, nicotinic acid and chemical derivatives of niacin". The amendment to claim 33, now states that included into the base formulation is "niacin, nicotinic acid, niacinamide and its derivatives", these now being the basis of dependent claim 48 which establishes chemicals as a basis for this Markush group all categorized as said "niacin derivatives".

Claim 59 has been amended to properly refer back to claim 33.

#### **3. Rejections: Prior Art & Obviousness 35 USC 103(a)/ 102(b)**

##### **A. Overview of the Claimed Invention:**

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Prior Art Rejections are tabulated as follows. In the left hand column is the prior art, inventor and formula component(s) as presented by the examiner and used as subject to the rejection. On the right hand side are the 28 possible combinations of the formulation. The base independent claim is comprised of the 6 essential elements with at least two of the markush group as listed in the left hand margin with all combinations present. These are the claim limitations. Therefore at a minimum, the formulation must contain 8 components. It is noted that none of these the prior art contain all the elements of the base claim combined with two of the markush group as an integrated formulation. Keep in mind that this formulation was designed to supercede efficacy of all the listed prior art, by combining essential elements of a base formula based on a observation, rationale and a hypothesis that is novel, and formulation as novel as described in this embodiment and as listed below.

Prior Art		Claim Limitations -Independent Claim 33			
102/103(a) Rejections		All Possible combinations			
Inventor	Prior Art Topic	Amended Base Claims 1-5		Markush <sup>7</sup>	Markush <sup>8</sup>
Yuuma	Tumeric	1	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Jacorico	St. Johns wort
Sciavoletto	Niacin and Aloe	2	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , <u>niacin<sup>5</sup></u> , aloe <sup>6</sup>	Chamomile	St. Johns wort
Engel	Black Walnut	3	<u>Black walnut<sup>1</sup></u> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	clove	St. Johns wort
Laforet	Black Walnut	4	<u>Black walnut<sup>1</sup></u> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	nutmeg	St. Johns wort
Otsuka	Propolis	5	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or <u>propolis<sup>3</sup></u> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	ginger	St. Johns wort
Kuch, Nishibe	St Johns Wort	6	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	frankincense	<u>St. Johns wort<sup>8</sup></u>
		7	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	myrrh	St. Johns wort
		8	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Licorice	Chamomile
		9	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or <u>propolis<sup>3</sup></u> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	<u>Licorice<sup>7</sup></u>	<u>clove<sup>8</sup></u>
Hidaka	Tumeric, clove, licorice, propolis	10	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Licorice	nutmeg
		11	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Licorice	ginger
		12	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Licorice	frankincense
Bombardelli	Myrrh	13	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Licorice	<u>myrrh<sup>8</sup></u>
		14	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Chamomile	clove
		15	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Chamomile	nutmeg
Xiefan	wormwood, garlic, ginger and chamomile	16	Black walnut <sup>1</sup> , <u>wormwood<sup>2</sup></u> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	<u>Chamomile<sup>7</sup></u>	<u>ginger<sup>8</sup></u>
		17	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Chamomile	frankincense
		18	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	Chamomile	myrrh
		19	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	clove	nutmeg
		20	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	clove	ginger
		21	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	clove	frankincense
		22	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	clove	myrrh
		23	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	nutmeg	ginger
		24	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	nutmeg	frankincense
		25	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	nutmeg	myrrh
		26	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	ginger	frankincense
		27	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	ginger	myrrh
		28	Black walnut <sup>1</sup> , wormwood <sup>2</sup> , garlic <sup>3</sup> or propolis <sup>3</sup> , tumeric <sup>4</sup> , niacin <sup>5</sup> , aloe <sup>6</sup>	frankincense	myrrh

## B. Relevant Obviousness Rejection Matters

1965 US Supreme Court case Graham v. John Deere Co., 383 U.S. 1, (1965), states that to support a 103(a) rejection:

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1. The claimed invention must be considered as a whole.
2. The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination.
3. The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.

The law states that rejections on obviousness grounds cannot be sustained by mere conclusory statements. "When obviousness is based on the teachings of multiple prior art references, and to support a *prima facie* case rejection, the movant must also establish some "suggestion, teaching, or motivation" that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed. *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1359-60 (Fed. Cir. 1999); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1572 (Fed. Cir. 1996)." *Teleflex, Inc. v. KSR Int'l*, 119 Fed.Appx. 282, 285 (Fed. Cir. 2005). See also *Al-Site Corp., v. VSI Int'l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999); *Yamanouchi Pharmaceutical Co., Ltd., v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1343 (Fed. Cir. 2000).

Further, to reach a non-hindsight obviousness rejection as to whether a person having ordinary skill in the art at the time of the invention, the office must have viewed the subject matter as a whole, provide rationale through articulation, using evidence supplying detailed analysis of the prior art for reasonable basis as to why the conclusion of legal obviousness is correct. See *Lee*, 277 F.3d at 1343-46; *Rouffett*, 149 F.3d at 1355-59.

In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but rather the **general problem that confronted the inventor before the invention was made**. See, e.g., *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323 (Fed. Cir. 2005) "Although the suggestion to combine references may flow from the nature of the problem, 'defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.'" *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998); *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992). Therefore, the "motivation-suggestion-teaching" test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, **and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.** See *Cross Med. Prods.*, 424 F.3d at 1321-24.

With that said, here is a brief overview of the claimed invention, the general problem that confronted the inventor before the invention was made, and scientific principles/rationale to solve that problem as discussed in the specification as filed.

#### **Over view of the currently claimed invention.**

In the claimed invention, scientifically valid reasoning was provided to combine the essential elements of the independent claim 33, which was not taught or evidenced by the referenced prior art. Again, there must be some suggestion or motivation, either in the nature of the problem to be solved,

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the teachings of the prior art, or the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings in order to stand behind an obviousness rejection. In brief overview, the rationale provided in this application was as follows:

In paragraph [0006], we explain that the problem appears to involve the following:

a) many dry skin diseases such as dyshidrosis stop at the perimeter of the hands and feet, indicating blood flow to extremities may be a central issue (rationalizing the need for incorporation into the composition, a natural agent that acts as a potent peripheral vasodilator).

b) dyshidrosis and other dry skin diseases appear to involve an unknown pathogenic component to which the etiological nature of the disease is not understood (rationalizing the need for incorporation in the composition, one or more natural robust anti-parasitic, anti-bacterial, anti-protozoal, anti-fungal, and anti-viral agent (s)). These agents also aid in creating a sterile environment, preventing infection where the dry skin diseases accompanies open wounds.

c) dyshidrosis and other dry skin conditions appear to escape the capability of our immune system to aid in healing (need for further incorporation of natural agents that mediate anti-inflammatory, anti-allergic effects and assist in the treatment of auto-immune diseases where the body attacks its own flesh such as lupus).

d) with dyshidrosis and other acute skin diseases, there appears to be extensive skin loss which can progress to equal that to a second degree burn (need for further incorporation of agents in the formulation that promote the rebuilding of healthy skin tissue, connective tissue or collagen or previous shown to aid in healing of thermal, chemical, or radiant skin burns).

e) dyshidrosis and other acute skin conditions can be painful, due to cracked open wounds, bleeding, and sores (rationalizing the need for incorporating into the composition a natural analgesics) and many dry skin diseases result from a lack of the body's own ability to moisturize skin via subcutaneous glands (need for further incorporation of a moisturizer).

f) lastly, with dyshidrosis and other dry skin diseases, the removal of dead skin can attenuate any potential inflammatory response against the body's own dead tissue (the need to further incorporate exfoliants). The medical term to those skilled in the art is called "debridement" where in the removal of dead, damaged, or infected tissue is known to improve the healing potential of the remaining healthy tissue." [Source: [http:// en.wikipedia.org /wiki / Debridement](http://en.wikipedia.org/wiki/Debridement)].

All of these mechanisms were researched and the formulation as designed was to include concomitant exposure to natural substances that serve as: NATURAL/HERBAL.

- 1) WOUND HEALING AGENTS
- 2) EXFOLIANTS
- 3) ANTI-ALLERGENS (EFFECTIVE AGAINST AUTOIMMUNE DISEASE)
- 4) ANTI-INFLAMMATORY AGENTS (COX, LOX INHIBITORS)
- 5) ANTI-PATHOGENIC AGENTS (ANTI-VIRAL, ANTIPARASITIC, ANTI-PROTOZOAL, ANTI-FUNGAL AND ANTI-BACTERIAL),

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- 6) ANALGESICS
- 7) MOISTURIZING AGENTS
- 8) VASODILATORY AGENTS
- 9) EFFECTIVE BURN TREATING AGENTS.

This combination, as novel, was found effective in treating a disease in which many individuals suffer with no effective standard medicinal treatments or over the counter ointments.

Rationale for provision of claimed substances, include a composition containing the following where rationale was provided in the specification as filed:

(1) Antibacterial, anti-parasitic, anti-protozoa, anti-fungal and anti-viral agents (wormwood discussed in P [00010, 00011]) (Black walnut discussed in P [00012]) (St Johns wort discussed in P [00013, 00014, 00015]) (Turmeric discussed in P [00016, 00017, 00018]) and (Propolis discussed in P [00019]). (Garlic – well known to those skilled in the art).

(2) Dermal anti-inflammatory agents such as COX, LOX inhibitors: (St Johns wort discussed in P [00013, 00014, 00015]) (Turmeric discussed in P [00016, 00017, 00018]) (Propolis discussed in P [00019]) and (Licorice which is well known to those skilled in the art due to its cortisone like properties attributable by glycyrrhizin which has a structure similarity to adrenal gland hormones).

(3) Agents that are effective against auto-immune diseases where the body attacks its own tissue such as lupus and/or serve as an anti-allergen: (Black walnut discussed in P [00012]) (St Johns wort discussed in P [00013, 00014, 00015]) and (Propolis discussed in P [00019]).

(4) Vasodilators: (Aloe Vera discussed in P [00032]). Niacin, is well known to those skilled in the art and is probably one of the most unique and potent natural sources capable of inducing peripheral vasodilation, effects mediated by prostacyclin. It is well known that niacin can cause "skin flushing effects" by promoting vasodilatory effects through augmenting endothelial relaxing factor/ nitric oxide in blood vessels in a similar fashion to garlic. (See: Benyo Z, Gille A, Bennett CL, Clausen BE, Offermanns S. Nicotinic acid-induced flushing is mediated by activation of epidermal langerhans cells. Mol Pharmacol. 2006 Dec;70(6):1844-9; Barakat MR, Metelitsina TI, DuPont JC, Grunwald JE. Effect of niacin on retinal vascular diameter in patients with age-related macular degeneration. Curr Eye Res. 2006 Jul-Aug;31(7-8):629-34.; Weiss N, Ide N, Abahji T, Nill I, Keller C, Hoffmann U. Aged garlic extract improves homocysteine-induced endothelial dysfunction in macro- and microcirculation. J Nutr. 2006 Mar;136(3 Suppl):750S-754S.)

(5) Compounds that promote the synthesis of collagen matrix, and promote healing of damaged skin tissue, in particular burns where layers of skin tissue are destroyed as in the case with pompholyx: (wormwood discussed in P [00010, 00011]), (St Johns wort discussed in P [00013, 00014, 00015]) (Turmeric discussed in P [00016, 00017, 00018]) (Propolis discussed in P [00019]) [Chamomile discussed in P [00022, 00023]) (Licorice discussed in P [00027]) and (Aloe Vera discussed in P [00032]), also see: Heggers JP, Kucukcelebi A, Listengarten D, Stahenau J, Ko F, Broemeling LD, Robson MC, Winters WD. Beneficial effect of Aloe on wound healing in an excisional wound model. J Altern Complement Med. 1996 Summer;2(2):271-7.

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(6) Compounds that remove dead skin (exfoliates and skin peels) which correlate with rapid healing of healthy skin tissue. (Chamomile discussed in P [00022,00023]) and (Garlic discussed in P [00024]).

(7) Moisturizing effects on the skin and/or analgesics: (Garlic discussed in P [00024]), (St Johns wort discussed in P [00013,00014,00015]), (Tumeric discussed in P [00016,00017,00018]), (Propolis discussed in P [00019]), (Chamomile discussed in P [00022,00023]) and (Niacin discussed in P [00029-31]).

(8) Additional anti-bacterial agents: discussed in P [00047], ginger, nutmeg, clove, myrrh and frankincense.

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**First rejection presented by office:**

**Rejection 1: Claims 33,35-38,41,42,44-47,50,52,56 and 58 are rejected under 35 USC 103(a) as being unpatentable over Xiao-fan et al., (U) in view of Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559) and Scivoletto (AA1, US 6,248,763 B1).**

a. Xiao-fan teaches: a composition for dry skin disorders comprising: wormwood, garlic, ginger and chamomile. **(Absence by Xiofan where formulation does not teach and contains: no black walnut<sup>1</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup>).** [4 base components of claim 33 missing]

b. Hidaka teaches a topical skin care composition comprising primarily tumeric 0.5-20% (+ licorice, clove, propolis) and a variety of oils **(Absence by Hidaka where formulation does not teach and contains: no black walnut<sup>1</sup>, no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup>).** [6 base components of claim 33 missing]

c. Yuuma teaches a topical skin care composition: tumeric (0.01-20%), and carriers, as a form of lotion, aerosol, cream and liquid. **(Absence by Yuuma where formulation does not teach and contains: no black walnut<sup>1</sup>, no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and none of the listed markush group herbs in category <sup>7,8</sup>).** [6 base components missing, no markush group components]

d. Scivoletto teaches a skin care composition of aloe (35-45%), niacin (.01-1%) combined with a carrier. **(Absence by Scivoletto where formulation does not teach and contains: no black walnut<sup>1</sup>, no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no tumeric<sup>4</sup> and none of the markush group herbs <sup>7,8</sup> as listed).** [5 base components missing, and no markush group components]

It was written that "At the time of the invention, one of ordinary skill in the art would have had a reasonable expectation of success to add tumeric (Hidaka and Yumma) aloe and niacin (Scivoletto) to a composition, where Hidaka teaches that compositions comprising effective amounts of turmeric are useful in treatment of dry skin diseases, Yumma teaches that tumeric is effective to treat a variety of skin disorders and Scivoletto teaches a skin care composition of only niacin and aloe, making this *prima facie* obvious in the absence of evidence to the contrary."

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### **Overturing 103 Obviousness Rejection:**

**Legal Relevance:** The prior art references (or references when combined) must teach or suggest all the claim limitations of the base claim. The teachings or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention and the office must present a convincing line of reasoning as to why the artisan would have found that the combination of the claimed invention would have been obvious in light of the teachings of the references. 35 U.S.C. §103 Conditions for Patentability; Non-Obvious Subject Matter," Manual of Patent Examining Procedure (MPEP), Edition 8 (F8), August, 2001. The office must provide evidence by specifically pointing out all of the claim limitations of the base claim by the prior art references by citing the sentences that teach each claim limitation. The office's rationale must be based on implicit disclosure, scientific principles, art-recognized equivalents, or legal precedent if the facts of the case are reasonably similar to those in the application.

**Overturing rejection-** In this application, not all of the claim limitations of claim 33 were found in any of the cited prior art, and a scientifically valid reason to combine was also lacking. Where the premise of this invention is based on combined underlying medicinal principles, Sivoletto teaches a composition comprised of aloe vera (useful for rebuilding of collagen and healing) an otherwise well known fact, and niacin (useful for promoting blood flow to a topical skin area), another well known fact, but Sivoletto's teachings are limited where the formulation does not include any useful agents that may serve to 1) antagonize inflammation 2) antagonize the underlying etiology of skin disease processes 3) antagonize a potential autoimmune response (autoimmune disease) or 4) remove dead skin to which the body response with immunological attack. Hidaka and Yuuma teach the use of tumeric either alone or combined with propolis (immunological stimulator), licorice (anti-inflammatory) and clove (anti-bacterial). However, neither teach or make reference to a concomitant presence of 1) (an exfoliate) for example garlic 2) (a collagen synthesis promoting agent i.e. aloe vera) or 3) (a vasodilatory agent) (i.e. niacin), an otherwise critical component that would in effect promote blood flow to the area of injury. While Xiofan teaches a composition for dry skin disorders comprising: wormwood, garlic, ginger and chamomile, which should in theory be effective against skin parasites, fungus and bacteria, Xiofan does not integrate 1) niacin as a vasodilator 2) a moisturizing agent 3) or aloe vera as a skin rebuilding agent to promote the synthesis of the healthy tissue. All of which are concomitant critical components of this invention to combat skin disease. Further, Xiofan utilizes only two of the six essential components of the base composition as in claim 33. Not all of the claim limitations are found in the cited prior art and a scientifically valid reason to combine was not provided.

**Rejection 2. Claims 33-38,41,42,44-47,49-52,56 and 58 are rejected under 35 USC 103(A) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 201-002559) and Scivoletto (AA1, US 6,248,763 B1) in view of Engel et al. (B\*), Wixforth (C\*), Rosen (D\*) and Laforet (E\*). Newly applied as necessitated by amendment.**

Notes: the teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto would make this obvious to one of ordinary skill in the art because black walnut is known in the art of herbal medicine being useful in skin care compositions by evidence taught by Engel, Wixforth, Rosen and Laforet.

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Engel teaches a composition of 40% black walnut oil. (Absence by Engel where formulation does not teach the integration and contains: no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and none of the markush group as listed in category <sup>7-8</sup>).

Rosen teaches composition comprising juglones and 5-hydroxy-1,4, naphthoquinone to treat dermatitis. (Absence by Rosen where formulation does not teach the integration and contains :no blackwalnut<sup>1</sup> no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and none of the markush group as listed in category <sup>7-8</sup>).

Wixforth teaches extracting 5-hydroxy-1,4 naphthoquinone having germicidal properties to make cosmetic preparations such as foot powders. (Absence by Wixforth where formulation does not teach and contains a chemical and :no blackwalnut<sup>1</sup> no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and none of the markush group as listed in category <sup>7-8</sup>).

Laforet teaches extract of Juglans regia to make a skin care composition having anti-inflammatory properties. (Absence by Laforet where formulation does not teach and contains : no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and none of the markush group as listed in category <sup>7-8</sup>).

It is written that "One of ordinary skill would have been motivated and had reasonable expectation of success to add either black walnut by teachings of Xiao-fan, Hidaka, Yuuma and Scivoletto to provide the instantly claimed invention. Each of Engle, Wixforth, Rosen and Laforet taught that the claimed ingredients were useful for making a skin care composition, which had anti-bacterial, anti-inflammatory, anti-collagenase, anti-elastase, anti-apoptotic and moisturizing effects."

#### **Overturning the obviousness rejection.**

Not all of the claim limitations are found in the cited prior art and a scientifically valid reason to combine was not provided. While the use of black walnut has been established, (its properties being an anti-collagenase, an anti-elastase, antibacterial and anti-inflammatory agent), the invention as we describe in this application complements but adds significantly to the teachings. While anti-collagenase and anti-elastase properties of this substance would prevent the breakdown of skin tissue, its being used in a specific formulation has not been taught that would include provision for incorporating substances of this invention which also include 1) agents that re-build collagen 2) agents that increase cutaneous blood flow 3) agents that exert anti-viral, anti-fungal, anti-parasitic properties and 4) and exfoliating agents. These being four critical components to this invention. Simply adding agents by other individual and previous teachings would not have been obvious because of the inventions design was to include all of the above to maximize efficacy treating both the etiology, remove dead skin, augment immune function, including incorporation of anti-allergens, anti-inflammatories, to increase blood flow to the site of injury, and to rebuild collagen rather than simply prevent its breakdown.

The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination of the reasonable expectation of success must both be found in the prior art, and not be based on applicant's disclosure.

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In other words, "all words in a claim must be considered in judging the patentability of that claim against the prior art." 6. In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970). The office must also explain any combination of teachings, if not reasonably apparent. The office must specifically point out all of the claim limitations in the references specifically citing the sentences that teach each claim limitation. The office's rationale must be based on implicit disclosure, scientific principles, art-recognized equivalents, or legal precedent if the facts of the case are reasonably similar to those in the application.

**Rejection 3.** Claims 33,35-39,41,42,44-47,50-53,56 and 58 are rejected under 35 USC 103(a) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 2001-002559) and Scivoletta (AA1, US 6,248,763 B1) in view of Otsuka et al. (RR, JP 10-175878).

The following teachings teach the claimed composition except for the ingredient of propolis. However, it would have been obvious to one skilled in the art to add this because Otsuka taught a composition comprising garlic in combination with propolis in amount of 10% to treat skin disorders for treatment of dermatitis, athlete's foot, scabies and skin diseases of dryness.

In this instance, Otsuka taught the use of propolis and garlic to treat fungal infections and dry skin, but does not teach and contains: no blackwalnut<sup>1</sup>, no wormwood<sup>2</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and none of the markush group as listed in category <sup>7-8</sup>).

**Overturning Rejection.** Not all of the claim limitations are found in the cited prior art and a scientifically valid reason to combine was not provided. The primary reason for including garlic into the formulation, is that to the inclusion of its well known anti-pathogenic properties, it removes dead skin. The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination of the reasonable expectation of success must both be found in the prior art, and not be based on applicant's disclosure. In other words, "all words in a claim must be considered in judging the patentability of that claim against the prior art." 6. In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970). The office must also explain any combination of teachings, specifically citing the sentences that teach each claim limitation. The office's rationale must be based on common knowledge in the art (implicit disclosure), scientific principles, art-recognized equivalents, or legal precedent if the facts of the case are reasonably similar to those in the application.

**Rejection 4:** Claims 33-38,41,42,44-47,49-52,54,56 and 58 are rejected under 35 USC 103(a) as being unpatentable over Xiao-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 201-002559) and Scivoletto (AA1, US 6,248,763 B1) in view of Koch et al. (SS, DE 10131641) and Nishibe et al. (TT, JP 09-157176). Newly applied as necessitated by amendment.

The office notes that these four teach the instantly claimed invention, with exception of St Johns wort, stating it would have been obvious to one skilled in the art to add the by teachings of Koch and Nishibe neither which teach and contains: no blackwalnut<sup>1</sup>, no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and an absence of at least one of the markush group as listed in category <sup>7</sup>).

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**Overturning obviousness.** As stated in rejection 1, Xio-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 201-002559) and Scivoletto (AA1, US 6,248,763 B1

- a. Xio-fan teaches: composition for dry skin disorders comprising: wormwood, garlic, ginger and chamomile. **(Absence by Xiofan where formulation does not teach and contains: no black walnut1, no tumeric4, no niacin5, no aloe vera6).** [4 base components of claim 33 missing]
- b. Hidaka teaches a topical skin care composition comprising primarily tumeric 0.5-20% (antioxidants licorice, clove, propolis) and a variety of oils **(Absence by Hidaka where formulation does not teach and contains: no black walnut1, no wormwood2, no garlic3, no niacin5, no aloe vera6).** [6 base components of claim 33 missing]
- c. Yuuma teaches a topical skin care composition: tumeric (0.01-20%), and carriers, as a form of lotion, aerosol, cream and liquid. **(Absence by Yuuma where formulation does not teach and contains: no black walnut1, no wormwood2, no garlic3, no propolis3, no niacin5, no aloe vera6 and none of the listed markush group herbs in category 7, 8).** [6 base components missing, no markush group components]
- d. Scivoletto teaches a skin care composition of aloe (35-45%), niacin (.01-1%) combined with a carrier. **(Absence by Scivoletto where formulation does not teach and contains: no black walnut1, no wormwood2, no garlic3, no propolis3, no tumeric4 and none of the markush group herbs 7,8 as listed).** [5 base components missing, and no markush group components]

**Overturning the rejection:** Not all of the claim limitations are found in the cited prior art and a scientifically valid reason to combine was not provided. Both Koch and Nishihe teach that use of St Johns wort extract is effective to treat skin diseases by various conventional pharmaceutical forms, however St Johns wort is not an essential part of the base claim, and is only one listed in the markush group, where none of the previously noted Either Xio-fan, Hidaka, Yuuma or Scivoletto teaches the essential elements of the base claim 33 to begin with. The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination of the reasonable expectation of success must both be found in the prior art, and not be based on applicant's disclosure. In other words, "all words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970). The office must also explain any combination of teachings, if not reasonably apparent, specifically citing the sentences that teach each claim limitation. The office's rationale must be implicit disclosure, scientific principles, art-recognized equivalents, or legal precedent if the facts of the case are reasonably similar to those in the application.

**Rejection 5.** Claims 33-38,41-47,49-52 and 56-58 are rejected under 35 USC 103(a) as being unpatentable over Xio-fan et al. (U), Hidaka (PP, JP 09-143086), Yuuma et al. (QQ, JP 201-002559) and Scivoletto (AA1, US 6,248,763 B1) in view of Bombardelli et al. (A). Newly applied as necessitated by amendment.

**Overcoming rejection:** Not all of the claim limitations are found in the cited prior art and a scientifically valid reason to combine was not provided. Bombardelli teaches a skin care

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composition comprising Commiphora mukul for treatment of skin diseases. (Absence by Bombardelli, where formulation does not teach and contains: no black walnut<sup>1</sup>, no wormwood<sup>2</sup>, no garlic<sup>3</sup>, no propolis<sup>3</sup>, no tumeric<sup>4</sup>, no niacin<sup>5</sup>, no aloe vera<sup>6</sup> and is missing at least one the markush group herbs<sup>7,8</sup> as listed). Bombardelli, only includes one of the optional markush group constituents, without incorporation all the elements of the base formulation. The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination of the reasonable expectation of success must both be found in the prior art, and not be based on applicant's disclosure. In other words, "all words in a claim must be considered in judging the patentability of that claim against the prior art." 6. In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970). The office must also explain any combination of teachings, if not reasonably apparent. The office must specifically point out all of the claim limitations in the references specifically citing the sentences that teach each claim limitation. The office's rationale must be based on implicit disclosure, scientific principles, art-recognized equivalents, or legal precedent if the facts of the case are reasonably similar to those in the application.

#### **Overturning rejection in view as a whole.**

Rouffett, 149 F.3d at 1355 makes reference that most inventions, arise from a combination of old elements and each element may often be found in the prior art. Id. at 1357. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. Id. at 1355, 1357.

In order to establish a *prima facie* case of obviousness based on a combination of elements as of the base claim 33, the office must establish basis for and "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." Id. at 1357-59. This entails consideration as to evidence, and referenced sentences which delineate teaching and scientific principle to where the "scope and content of the prior art" makes that obvious to "level of ordinary skill in the pertinent art." To support the conclusion that the claimed invention is directed to obvious subject matter, either **the references must expressly or impliedly suggest the claimed invention** or the office must present convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references" 7. "35 U.S.C. §103 Conditions for Patentability; Non-Obvious Subject Matter," Manual of Patent Examining Procedure (MPEP), Edition 8 (E8), August, 2001, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination". "The suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness." ACS Hospital Sys., Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577 (Fed.Cir. 1984).

The case of non-obviousness is exemplified in the 1965 US Supreme Court case Graham v. John Deere Co., 383 U.S. 1, (1965). This case and subsequent jurisprudence have established factual inquiries of obviousness:

1. The claimed invention must be considered as a whole

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2. The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination

3. The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention

1965 US Supreme Court case Graham v. John Deere Co., 383 U.S. 1, (1965).

Also, in the assessment of an obvious rejection under § 103, the Board follows precedence as described in Supreme Court Graham v. John Deere Co. Graham, 383 U.S. at 17. In making this determination, the board also considers underlying evidence related to non-obviousness like "commercial success, long felt but unresolved needs, failure of others, etc." Id., 383 at 17-18; accord Rouffett, 149 F.3d at 1355.

(A) **Failure of others:** Failure by others to move forward to market a formulation as presented in this embodiment, is evident by the lack of sold or marketed products such as this to the public. Options available and sold are standard triple antibiotic treatments, pain relief (ie topical lidocaine), moisturizers, other herbal formulations as discussed in the specification often adulterated with prescriptive steroids, and aloe vera based gels. There is a need to move to market such an effective cream as to ameliorate those suffering individuals who have no effective options remaining to combat dry skin disorders. Meanwhile many suffer from dyshydrosis, without any available treatment options, often leading to debilitation also supporting what is construed as a **long felt unresolved need.**

(B) **Commercial Success:** There is a great need to manufacture an effective topical formulation to be administered with or without adjunct oral intake of non-flush free niacin, as there are many people who experience human suffering without any effective alternative medicines available.

#### ISSUES TO OVERTURN POTENTIAL NEW MATTER GROUNDS AS PRESENTED IN THE AFTER FINAL AMENDMENT

1. In the specification all ingredients discussed throughout are discussed to support the claim limitations within claim 33 and to be included into the formulation, with the exception of propolis which as stated in 00019 is optional as follows for the following reasons:

[00019] **INGREDIENT 5:** Propolis is an optional ingredient in this formula. It was not incorporated into the base formula as tested, however, it may be used as a substitute to replace ingredients that may otherwise cause allergic skin reactions such as garlic, or to enhance efficacy or aesthetic properties

2. The working example of the formulation as provided in the original disclosure in P 00048, also shows support that the specification matches all the claim limitations of the current claim 33, where garlic is listed in lieu of propolis given the reasons explained in P 00019 above.

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[00048] The ingredients that comprise a working example of the formula, as listed below are presented as % total weight herein specified as "%TW" with extended (EXT) ranges. This is a preferred working example due to efficacy established in case study.

Working Example:			
	% TW	EXT. Range (% TW)	
<sup>1</sup> <u>Wormwood (<i>Artemisia Absinthium</i>) Extract</u>	9 %	0.5 %	- 90 %
<sup>2</sup> <u>Black Walnut Hull (<i>Juglans Nigra</i>) Extract</u>	9 %	0.5 %	- 90 %
<sup>3</sup> <u>Turmeric (<i>Curcuma Longa</i>) Extract</u>	7 %	0.5 %	- 90 %
<sup>4</sup> <u>Garlic (<i>Allium Sativum</i>) or Propolis Dry or Extract</u>	10 %	0.75 %	- 70 %
[Markush Group 7-8] Licorice ( <i>Glycyrrhiza Glabra</i> ) Extract	3 %	0.5 %	- 25 %
[Markush Group 7-8] St Johns Wort ( <i>Hypericum</i> ) Extract	3 %	0.5 %	- 25 %
[Markush Group 7-8] Chamomile ( <i>Matricaria</i> ) Extract	2 %	0.5 %	- 25 %
[Markush Group 7-8] *Antibacterial Agent	2 %	0.5 %	- 25 %
<sup>5</sup> <u>Niacin</u>	1 %	0.02 %	- 5 %
<sup>6</sup> <u>100% Pure Aloe Vera or *DAC</u>	54 %	5 %	- 95 %
TOTAL	100 %		

\*DAC (Dermatological acceptable Carrier),  
in which aloe vera is also listed: see original claim 16

[Markush Group] \*Optional Antibacterial Agents: Clove, Ginger, Nutmeg, Myrrh

3. The rationale and the original specification as filed as per P [0006] support aloe vera to be a critical component to the invention, as it is the only listed agent in the rationale section. See line 19-20

[0006] The embodied invention discloses a novel topical formulation, found effective in establishing complete remission in a pilot trial of severe dyshidrosis, non-responsive to current prescription medicines and over the counter ointments. Moreover, the formula was found to be effective in rapidly suppressing and reversing initial symptoms of outbreak. Results indicate that therapy can be discontinued after remission is established. The principles governing development of the embodied formulation were based on observations regarding pathological symptoms of the disease: A) this skin disease stops at the perimeters of the hands and feet, indicating reduced circulation or blood flow may play a role B) this condition appears to involve an unknown factor, with an intermittent nature, that thrives on both moisture and flesh, possibly a virus C) this condition escapes capability of our immune system to destroy it and D) there is extensive skin loss, somewhat similar to a second degree burn. For these reasons, the topical ointment was formulated to (1) contain anti-microbial: anti-parasitic, anti-bacterial, anti-protozoal, anti-fungal and anti-viral properties to destroy or inhibit the growth of invading pathogenic organisms or potential unknown retroviruses (2) contain dermal anti-inflammatory agents: effective cyclooxygenase inhibitors / lipoxygenase inhibitors, and compounds that attenuate local dermal eicosanoids and prostaglandins to reduce the swelling, redness and pain (3) contain cutaneous vasodilators that inhibit thromboxanes, and increase local endothelial nitric oxide to increase blood flow to the area of injury

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**(4) contain aloe vera gel as a base in order to promote rapid healing of damaged or lost skin tissue and (5) contain compounds that destroy or remove dead skin, which appear to correlate with rapid healing.**

4. As per [P 00032] in the original specification as filed, aloe is again listed as an ingredient.

**[00032] INGREDIENT 10:** Aloe has well known effects on the skin, including positive effects on cell regeneration and growth of epidermal tissue. (Choi, S.W., Son, B.W., Son, Y.S., Park, Y.I., Lee, S.K., Chung, M.H., Br J Dermatol 2001 45:535-45). Aloe can increase blood flow to the skin, and promote rapid healing of damaged skin tissue (Somboonwong, J., Thanamitramanee, S., Jariyapongskul, A., Patumraj, S. Med Assoc Thai 2000 83:417-25; Visuthikosol, V., Chowchuen, B., Sukwanarat, Y., Sriurairatana, S., Boonpucknavig, V. J Med Assoc Thai 1995 78:403-9). One of the major therapeutic properties of aloe, include its ability to increase collagen, dermatan sulphate and glycosaminoglycans (Chithra, P., Sajithlal, G.B., Chandrakasan, G. Mol Cell Biochem 1998 181:71-6; Chithra, P., Sajithlal, G.B., Chandrakasan, G. Indian J Exp Biol 1998 36:896-901; Chithra, P., Sajithlal, G.B., Chandrakasan, G. J Ethnopharmacol 1998 59:179-86).

**Required amendment to the specification P [00048] and claim 47, listing aloe vera AS a dermatologically acceptable carrier:**

Since aloe vera is a critical component to the invention as implied throughout the specification, and presented in the working example as the largest by weight constituent, the term or does not negate its presence as exemplified and it is also listed under the category of dermatological acceptable carrier as of claim 16. We amend the specification as follows to where aloe vera is now stated as aloe vera and optionally a dermatologically acceptable carrier, now absence the listing for aloe vera as a dermatological acceptable carrier.